Remarks

Status of Claims

Claims 1, 5-9, 11-16, 18-20, 22, 23, and 28-37 are presently pending in the application, claims 2-4, 10, 17, 21 and 24-27 having been canceled and claims 33-37 having been added. Claims 13 and 30 have been withdrawn by the Examiner, thus claims 1, 5-9, 11-12, 14-16, 18-20, 22-23, 28-29 and 31-37 are presented for examination.

Support for new claims 33, 34 and 37 can be found, for example, in paragraph [0081] of the specification. Support for new claims 35 and 36 can be found, for example, in original claim 14. No new matter is added.

Withdrawn Rejections

Applicant notes, with thanks, the Examiner's withdrawal of the rejection of claims 1, 4-9, 17 and 21 under 35 U.S.C. §103(a) over Kamath.

Applicant notes, with thanks, the Examiner's withdrawal of the rejection of claims 10-16, 18-19 and 21-23 under 35 U.S.C. §103(a) over Kamath in view of Kumar.

Applicant notes, with thanks, the Examiner's withdrawal of the rejection of claim 20 under 35 U.S.C. § 103(a) over Kamath in view of Zukowsky.

Rejection under 35 U.S.C. 103(a) – Pinchuk, Smith and Hamilton

Claims 1, 5-9, 11-12, 14-16, 18-20, 22-23, 28-29 and 31-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pinchuk, US 6,545,097 (Pinchuk), Smith et al., US 5,639,810 (Smith) and Hamilton et al., US 6,896,842 (Hamilton). Applicant respectfully traverses this rejection.

For a proper obviousness rejection under 35 U.S.C. 103, the differences between the subject matter sought to be patented and the prior art must be such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which the subject matter pertains. 35 U.S.C. §103. The key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. MPEP 2141. " '[R]ejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with

some rational underpinning to support the legal conclusion of obviousness.' " *KSR International Co.* v. *Teleflex Inc.*, 550 U.S. ___, 82 USPQ2d 1385 (2007), quoting *In re Kahn ,* 441 F.3d 977, 988, (Fed. Cir. 2006). It should be noted that the prior art reference (or references when combined) must teach or suggest all the claimed features. "When determining whether a claim is obvious, an examiner must make 'a searching comparison of the claimed invention – *including all its limitations* – with the teaching of the prior art.' … Thus, 'obviousness requires a suggestion of all limitations in a claim.' …" *Ex parte Wada and Murphy*, BPAI Appeal No. 2007-3733, January 14, 2008 (emphasis in original) (citations omitted). In addition, there must be a reasonable expectation of success. See MPEP 2143.02.

Independent claim 1, the only independent claim presently pending, is directed to an implantable or insertable medical device comprising (a) a therapeutic agent and (b) *a polymeric carrier region that comprises said therapeutic agent and which releases said therapeutic agent upon administration to a patient*, said polymeric carrier region comprising *a silicone block copolymer* comprising a plurality of siloxane units and a plurality of non-siloxane units, said block copolymer *comprising (i) a block of said siloxane units* selected from a polydimethylsiloxane block, a polydiethylsiloxane block, a polymethylethylsiloxane block and a polymethylphenylsiloxane block *and (ii) a block of elevated T_g non-siloxane units*, wherein the polymeric release region is in the form of a coating layer that covers all or a part of said medical device.

According to the Office Action, Pinckuk teaches, *inter alia*, a composition for delivering therapeutic agents such as paclitaxel, which comprises a block copolymer made up of an elastomeric block and a thermoplastic block, and is used to coat at least a portion of an intravascular or intervascular medical device such as stent.

The Office Action notes that Pinchuk does not teach wherein the elastomeric block comprises polydimethylsiloxane, but urges (a) that Smith teaches thermoplastic block copolymers having methylstyrene end blocks and polydimethylsiloxane (elastomeric) intermediate blocks and (b) that Smith teaches that the elastomeric materials are useful for medical and therapeutic device applications.

More specifically, Smith describes elastomeric materials useful for medical and therapeutic device applications wherein there is a need for a penetrable sealing element such as a penetrable septum (see Abstract). The block copolymer taught by Smith for use in such

applications is a styrene-ethylene/butylene-styrene block copolymer (see, e.g., col. 2, lines 45-49, col. 8, lines 5-7, etc.).

Smith at cols. 4 lines 48 *et seq.* describes several prior art references which "may also be considered relevant to the present invention" including U.S. Pat. No. 4,123,409 to Klaelble. Klaelble describes a thermoplastic elastomer sealing material for contact with animal tissue, which is made by mixing a high molecular weight non-volatile oil in at least a ratio of 1 to 1 with a block copolymer. In a first embodiment, thermoplastic block copolymers having polystyrene end blocks and butadiene or isoprene intermediate blocks are combined with a hydrocarbon oil, e.g., mineral oil. In a second embodiment, thermoplastic block copolymers having polyalphamethylstyrene end blocks and polydimethylsiloxane intermediate blocks are combined with silicone oil. The specific silicone oil used in Klaelble is DC200 (Dow Corning 200) silicone oil, otherwise known as polydimethlysiloxane (see Klaelble at col. 5, lines 58-68 and the attached data sheet on DC200).

Thus the materials in Smith and Klaelble are sealing materials, with the Smith describing a penetrable sealing element (e.g., septum) and Klaelble describing a sealing material for use in contact with animal tissue, such as for sealing a stoma opening (see Klaelble Abstract).

Sealing materials, while useful for many medical applications, are clearly inappropriate for forming polymeric carrier regions like those claimed which comprise a therapeutic agent and which release the therapeutic agent upon administration to a patient. In fact, by their very nature, a sealing material is the very antithesis of a drug releasing polymeric carrier. In this way, Smith and Klaelble actually teach away from the present invention.

The concept of using a silicone block copolymer comprising a plurality of siloxane units and a plurality of non-siloxane units copolymers in polymeric carrier regions which comprise a therapeutic agent and which release the therapeutic agent upon administration to a patient is Applicant's concept and is unobvious in view of the prior art.

As stated in MPEP 2142: "The tendency to resort to "hindsight" based upon applicant's disclosure is often difficult to avoid due to the very nature of the examination process. However, impermissible hindsight must be avoided and the legal conclusion must be reached on the basis of the facts gleaned from the prior art." Here, the prior art does not support a conclusion of obviousness absent the hindsight gained from Applicant's disclosure.

Hamilton, which is cited for its teaching that thermoplastic elastomers for medical devices are resistant to radiation and can thus be sterilized by radiation, does not make up for the above-noted deficiencies in Pinchuk, Smith and Klaelble.

For at least the above reasons, claims 1, 5-9, 11-12, 14-16, 18-20, 22-23, 28-29 and 31-32 are patentable over Pinchuk, Smith, Klaelble and Hamilton.

Conclusion

Should the Examiner be of the view that an interview would expedite consideration of the application, request is made that the Examiner telephone the Applicants' attorney at (703) 433-0510 in order that any outstanding issues be resolved.

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ATTACHMENT